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510(K) SUMMARY: V.A.C® Therapy family of devices.

I. Name of Device: V.A.C.® ATS™, mini V.A.C.®, V.A.C.® Freedom™

II. Classification Name: **Powered Suction Pump**
21 CFR 878.4780

III. 510(k) Applicant:
Kinetic Concepts, Inc. (KCI)
8023 Vantage Drive
San Antonio, TX 78265-8508
Contact: Judith Harbour 1-800-275-4524

IV. Substantial Equivalence:
V.A.C. Plus
510(k) No.K992448
Ambulatory V.A.C.
510(k) No.K971548

V. Description of Device

All models of the VAC family of devices, including the V.A.C.® ATS™, mini V.A.C.®, and the V.A.C.® Freedom™, consist of a vacuum control unit with an integrated collection canister and power supply.

VI. Intended Use of the Device

The V.A.C.® family of devices are feedback-controlled negative pressure devices used to help promote wound healing, through means including vacuum assisted drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent suction pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. Feedback control is achieved by measuring the level of negative pressure at the wound site.

VII. Summary of the technological characteristics of the device compared to the predicate device.

Each of the devices in the V.A.C. family of devices consists of the same basic technology, and do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness. Each device consists of a vacuum control unit with an integrated collection canister and power supply (battery or AC). The primary differences in these models relate to size and weight. All models of the V.A.C. family of devices are designed to help promote wound healing, through the application of controlled negative pressure to the surface and margins of the wound. This negative pressure therapy is applied to the V.A.C. foam dressing positioned in the wound cavity or over a flap or graft. This pressure distributing foam dressing helps remove fluids from the wound. The devices are designed to treat wounds such as chronic, acute, traumatic, subacute and dehisced wounds; partial-thickness burns; ulcers (such as diabetic or pressure); flaps; and grafts.

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VIII. Testing

Verification and validation testing of the V.A.C. family of devices, including functional performance testing and electrical leakage testing, was conducted in accordance with established design control procedures.

IX. Conclusions

Based upon the testing and comparison to the predicate devices, the V.A.C. family of devices has the same intended uses, with similar technological characteristics. The system performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Ms. Judith Harbour
Regulatory Affairs Manager
Kinetic Concepts, Inc.
P.O. Box 659508
San Antonio, Texas 78216

Re: K032310
Trade/Device Name: The V.A.C.® family of devices: mini V.A.C.®, V.A.C.® Freedom™, V.A.C.® ATS™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: JCX
Dated: July 21, 2003
Received: August, 4, 2003

Dear Ms. Harbour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K023210

Device Name: The V.A.C.® family of devices:
mini V.A.C.®, V.A.C.® Freedom™, V.A.C.® ATS™

Indications For Use:

The V.A.C.® family of devices with woundsite feedback control are negative pressure devices used to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. Feedback control is achieved by measuring the level of negative pressure at the wound site.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X
(per 21 CFR 801.109)

OR

Over the Counter Use:
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023210